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| 10/784,352      | 02/23/2004  | Aaron T. Timperman   | 22085/2102          | 2338             |

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EXAMINER

BARTON, JEFFREY THOMAS

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1753

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

7

|                              |                               |                                     |  |
|------------------------------|-------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>10/784,352 | Applicant(s)<br>TIMPERMAN, AARON T. |  |
|                              | Examiner<br>Jeffrey T. Barton | Art Unit<br>1753                    |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 February 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12, 14, 18-23, 33, 37-41 and 43 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12, 14, 18-23, 33, 37-41 and 43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Response to Amendment***

1. The amendment filed on 7 February 2006 does not place the application in condition for allowance.

***Status of Rejection Pending Since the Office Action of 8 August 2005***

2. The rejection of claims 12, 14, 18-23, 33, 37-41, and 43 under 35 U.S.C. §112(1) is withdrawn due to Applicant's amendment.
3. All other rejections are maintained.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 12, 14, 18-22, 33, 37-39, 41, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xue et al in view of Karger et al and Lee et al.

Relevant to claim 12, Xue et al disclose a microfluidic bi-directional capillary electrophoresis device (Figure 7b), comprising: a middle column (24 and 25), the middle column intersecting a first channel and a second channel (26 and 27) at a point wherein the middle column is approximately perpendicular to the first and second channels (23), a negative electrode in communication with the first channel and a positive electrode in communication with the second channel (33), wherein a mixture of anions and cations may be separated by drawing them towards the electrodes of opposite polarity.

Relevant to claim 33, Xue et al disclose a method of separating a sample of anions and cations in a microfluidic capillary system, comprising: delivering the sample to the middle column of the device described above in addressing claim 12 (Paragraph 0071 - sample in 28 and vacuum applied to 29 would lead to sample traveling through channels 24 and 25), positioning negative and positive electrodes (33) in communication with the first and second channels, thereby drawing anions and cations into the channel corresponding to the electrode of opposite polarity (Paragraph 0071, Figure 9)

Relevant to claims 19, 20, 38 and 39, Xue et al disclose first and second detectors in communication with the first and second channels, for the detection of cations and anions, respectively. (Detectors 52 and 53, Figure 7B; Paragraph 0054)

Relevant to claims 21 and 41, Xue et al disclose hydrodynamic flow resistance through variation of cross-sectional area in any or all channels. (Paragraph 0038)

Relevant to claim 22, Xue et al disclose devices comprising a pressure outlet. (Paragraphs 0034 and 0040; Line 47, Figure 2)

Xue et al do not explicitly disclose a coated first channel, a coated second channel, or a first channel engaged to a microfluidic system for proteome analysis (Claims 12 and 33); a first channel coated with Triton X-100 (Claims 18 and 37); or a second channel engaged to a second microfluidic system for proteome analysis. (Claims 14 and 43)

Relevant to claims 12, 18, 33, and 37, Karger et al disclose capillary channels that have been coated with Triton X-100 in order to reduce electroosmosis in electrophoretic separations. (Column 5, lines 3-39)

Relevant to claims 12 and 33, Lee et al disclose microfluidic systems for two-dimensional protein separations in proteome analysis (e.g. Figure 3, Paragraph 0033)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the devices and methods of Xue et al by coating the first and second channels (26 and 27) with Triton X-100, as taught by Karger et al, because it would reduce electroosmosis. Such coatings would be an obvious modification of the devices and methods of Xue et al, because it would be desirable to minimize electroosmosis in such a system, wherein oppositely charged analytes migrate in opposite directions within a channel. Excessive electroosmosis would lead to a bulk

flow that prevents migration in one of the directions, or leads to undesirably long migration times, as would have been obvious to one having ordinary skill in the art.

It would also have been obvious to one having ordinary skill in the art at the time the invention was made to modify the devices and methods of Xue et al by placing the channels (26 and 27) in communication with sample inlets to proteome analysis systems, such as those taught by Lee et al, because it would provide a more powerful analytical tool with an additional dimension of separation. Because Xue et al and Lee et al are directed towards quite similar problems (i.e. separation of proteins by electrophoresis within capillary channels formed on a substrate), the examiner considers that it would have been within the abilities of a skilled artisan to incorporate such known related prior art channel geometries, connectivity, and separation strategies as taught by Lee et al into the system of Xue et al, given a protein sample of sufficient complexity that it would require multiple stages of separation.

Regarding the limitation in claims 12 and 33, "wherein the coating of the first channel and the coating of the second channel is applied in an amount and type to minimize sample loss", this would be an inherent property of the coating taught by Karger et al, since this coating substantially eliminates surface charge of the channel. [Karger, Column 6, line 56 - Column 7, line 33; this procedure will substantially eliminate surface -OH groups in any glass or silica channel, which are disclosed by Xue et al (Paragraph 0036)] Since surface -OH groups provide the source of charge on capillary walls and are the primary cause of sample loss as described by Applicant (Specification, page 3, line 25 - Page 4, line 23), a minimization of surface charge would

lead to minimization of sample loss. As further evidence, the Triton X detergent specifically claimed as the coating in claim 18 is disclosed by Karger et al. (Column 5, lines 34-39) Therefore, no patentable difference is seen between the instant claims and the combination given above.

7. Claims 23 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xue et al, Karger et al, and Lee et al as applied to claims 12 and 33 above, and further in view of Kopf-Sill et al.

Xue et al, Karger et al, and Lee et al disclose combined devices and methods as disclosed above in addressing claims 12 and 33.

None among Xue et al, Karger et al, and Lee et al explicitly disclose the use of a dual-channel detector in communication with the first and second channels.

Kopf-Sill et al disclose the use of multichannel detectors in communication with one or more channels within their microfluidic device. (Figure 13; Paragraphs 0036 and 0088)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combinations of the devices and methods of Xue et al, Karger et al, and Lee et al by adjusting the position of separation channels such that they ran parallel and adjacent to each other and positioning a dual channel detector in communication with the channels, as taught by Kopf-Sill et al, because it would eliminate the need for multiple detectors.

***Response to Arguments***

8. Applicant's arguments filed 7 February 2006 have been fully considered but they are not persuasive.

Regarding the limitation in claims 12 and 33, "wherein the coating of the first channel and the coating of the second channel is applied in an amount and type to minimize sample loss", Applicant again argues that Karger does not address the issue of sample loss, and therefore does not meet this new limitation.

As maintained above, minimization of sample loss as described by Applicant in the specification would be an inherent property of the coating taught by Karger et al, since this coating substantially eliminates surface charge of the channel. [Karger, Column 6, line 56 - Column 7, line 33; this procedure will substantially eliminate surface -OH groups in any glass or silica channel, which are disclosed by Xue et al (Paragraph 0036)] Since surface -OH groups provide the source of charge on capillary walls and are the primary cause of sample loss as described by Applicant (Specification, page 3, line 25 - Page 4, line 23), a substantial elimination of surface hydroxyls would lead to minimization of sample loss. In fact, the Triton X detergent specifically claimed as the coating in instant claim 18 is disclosed as a coating material by Karger et al. (Column 5, lines 34-39)

There simply is no physical difference seen between the system that is instantly claimed and the system taught by the combination of references. Excerpts from the respective disclosures can do nothing to convince the Examiner that the claims are patentable as currently recited. If a Triton X coating minimizes sample loss in the



instant system, it certainly will have done so in the prior art system as well, regardless of whether this property is discussed in the prior art.

### ***Conclusion***

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Jeffrey Barton, whose telephone number is (571) 272-1307. The examiner can normally be reached Monday-Friday from 9:00 am – 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached at (571) 272-1342. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Art Unit: 1753

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

JTB  
17 April 2006

  
**ALAN DIAMOND**  
**PRIMARY EXAMINER**  
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